DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

q1427d

MAY 31 2001

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Jean-Pierre Arnaudo
E-Med Innovations, Inc
5001 LBJ Freeway, Suite 930A
Dallas, Texas 75244

Dear Mr. Arnaudo:

The Food and Drug Administration's (FDA), Center for Devices and Radiological Health (CDRH) has reviewed the advertising brochure and your web site for e-steth digital stethoscope and CardioMail™ software. The e-steth digital stethoscope is a class II medical device (Title 21 Code of Federal Regulations (CFR) part 870.1875) that requires premarket notification and the CardioMail™ is a class I medical device (Title 21 CFR 870.2390) that is exempt from premarket notification.

Under a United States Federal law, the Federal Food, Drug and Cosmetic Act (the Act), the e-steth and CardioMail™ are considered to be medical devices because they are used to diagnose a medical condition. The law requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps to protect the public health by ensuring that newly introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance for your e-steth digital stethoscope before offering it for sale. The kind of information you need to submit to obtain this clearance is described in the enclosed materials. After you submit this information, FDA will evaluate it and decide whether your e-steth digital stethoscope may be legally marketed.

The FDA has exempted certain products from premarket notification. CardioMail™ has been exempted from premarket notification (21 CFR 870.2390).

Because you do not have marketing clearance for your e-steth digital stethoscope, marketing this product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is adulterated under the Act because you did not obtain premarket approval based on information developed by you

that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the QPD Panel, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know what steps you have taken to correct the problem within fifteen (15) working days from the date you receive this letter. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Heyward Rourk, Diagnostic Devices Branch, Office of Compliance (HFZ-322), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Dallas District Office. Please send a copy of your response to the District Director, Dallas District Office (HFR-SW140), 3310 Live Oak Street, Dallas, Texas 75204.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at http://www.fda.gov.

If you have specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Heyward Rourk at (301) 594-4591.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health